#### REMARKS

### **Examiner Interview**

Applicant appreciates the courtesy shown by the Examiner in granting a telephone interview on 31 March 2008. The amendments above and response that follows takes account of discussions that took place in the interview.

# Amendments in the claims

Following amendment as requested herein, the following claims are pending in the present application: Claims 1, 5-10 and 18-28. Claims 2, 3, 11, 16 and 17 have been cancelled herein. New Claims 25-28 have been added herein. Matter not originally filed with this specification, *i.e.* new matter, is not introduced by the present amendment and no change in inventorship is believed to result. Specifically:

Claim 1 is amended herein to focus on an embodiment of the invention wherein the transgenic oviparous fish is breed with a fish selected from a different species with different phenotype or pattern, and wherein the transgenic fish and the fish with different phenotype or pattern are in the same genus. This amendment is supported at least by originally filed Claims 2 and 3. Further, this amendment is made to reduce the number of issues in prosecution. No admission is made that Claim 1 as previously presented is not patentable, and Applicants may elect to reintroduce all or part of the deleted subject matter in a continuing application.

Claims 2, 3, 11, 16 and 17 are cancelled herein.

Claims 18, 19 and 20 are amended herein to coincide with the amendments made to Claim 1.

Claim 18 is further amended to clarify the genus and species recited therein as suggested by the Examiner.

New Claims 25-28 are added herein. New Claims 25-28 are supported by Applicants' specification as filed at least at pages 4-5, corresponding to [0022]-[0026].

### RESPONSE TO OFFICE ACTION DATED 11 JANUARY 2008

# 1. Rejection under 35 U.S.C. §112, first paragraph

Claims 1-3, 5-11 and 16-24 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Specifically, the present rejection is maintained on the grounds that the claims continue to encompass intergenus matings as well as interfamily matings. Claims 2, 3, 11 and 16 have been cancelled, therefore the rejection as to those claims is moot. Applicants have amended Claim 1 to focus on an embodiment of the invention wherein the transgenic oviparous fish is breed with a fish selected from a different species with different phenotype or pattern, and wherein the transgenic fish and the fish with different phenotype or pattern are the same genus. The present rejection is now moot as this embodiment does not encompass intergenus as well as interfamily matings. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. §112, first paragraph.

# 2. Rejection under 35 U.S.C. §112, second paragraph

Claims 1-3, 5-11 and 16-24 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "screening the transgenic progeny that exhibit for those exhibiting..." is unclear. Claims 2, 3, 11 and 16 have been cancelled, therefore the rejection as to those claims is moot. Applicants have amended the phrase in Claim 1 to read "screening the transgenic progeny for those exhibiting...". Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. §112, second paragraph.

### 3. Rejection under 35 U.S.C. §102(b)

Claims 1, 2, 5-9 and 23 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Hsiao C., et al. (already made of record). Claim 2 has been cancelled therefore the rejection as to that claim is moot. Further, Applicants have amended Claim 1 to focus on an embodiment of the invention wherein the breeding is performed between different species

fish (interspecies). Hsiao is limited to breeding performed using the same species. Therefore, Hsiao does not teach each and every element of instant Claim 1. Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. §102(b).

# 4. Rejection under 35 U.S.C. §103(a)

# 4.1 Rejection of Claims 1, 2, 5-9 and 23

Claims 1, 2, 5-9 and 23 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Hsiao C., et al. in view of Lawson N. and Weinstein B. (already made of record). This rejection is respectfully traversed. Claim 1, as amended herein recites a method for generating an adult oviparous teleost ornamental fish, comprising, among others, breeding a transgenic oviparous fish with a fish selected from a different species with different phenotype or pattern to obtain transgenic progeny, wherein the transgenic fish and the fish with different phenotype or pattern are the same genus.

# 4.1.1 No motivation to combine

The Action maintains "It would have been obvious to combine the teachings of Hsiao in making a transgenic fish exhibiting stable and reproducible fluorescent reporter gene expression with those of Lawson and Weinstein to mate the transgene of Hsiao into an albino mutant fish. One of skill in the art would have been so motivated to obtain a fish exhibiting a fluorescent pattern that is not obscured by the natural pigment pattern of the fish." (present Action, page 7, lines 10-14) However, the fish species used by Hsiao is *Danio rerio*, which is the same species used in Lawson and Weinstein. If one of ordinary skill in the art were to combine Hsiao with Lawson and Weinstein (although no such motivation is admitted herein) the combination of teachings of Hsiao and teachings of Lawson and Weinstein would not lead to the presently claimed invention. Both Hsiao and Lawson and Weinstein only report intraspecies mating, as opposed to interspecies (between different species) mating. Claim 1 as amended herein, focuses on an embodiment of the invention wherein breeding is interspecies. Therefore, no motivation exists in Hsiao and Lawson and Weinstein or in the general art to arrive at the present invention.

# 4.1.2 No reasonable expectation of success

Even if motivation did exist to combine Hsiao and Lawson and Weinstein (which is not admitted herein), there is no reasonable expectation of success. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been <u>predictable</u> to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 385 (2007) (emphasis added). In this case, Applicants submit that the results were clearly unpredictable for the following reasons:

- "Matings of distantly related species of the same genus...are highly unpredictable as to the success of the fertilization, development, health of any progeny that do occur and fertility of offspring." (see present Action, page 3, lines 9-11) Instant Claim 1 recites breeding between different species of the same genus.
- "Hybridization between species often results in offspring that are sterile or with diminished reproductive capacity as a result of problems in gonad development and chromosome pairing. The results of inter-specific hybridization can lead to unexpected and undesirable results and can depend on the genetic structure of the parent fish." (see present Action, page 3, lines 12-15, citing Bartley et al.)
- "While inter-specific mating of certain species is known to result in various, desirable outcomes, these combinations are not easily arrived at, as evidenced by the mating of various species of grouper [citing Bartley *et al.*]." (see present Action, page 3, lines 16-18)

Therefore, Applicant submits that one of ordinary skill in the art could not possibly have a reasonable expectation when breeding between different species as is currently recited in Claim 1.

#### 4.2 Rejection of Claims 2 and 3

Claims 2 and 3 stand rejected under 35 U.S.C. §103 as allegedly obvious over Hsiao in view of Bartley *et al.* (already made of record) and Gong *et al.* (already made of record). Claims 2 and 3 are cancelled herein therefore the rejection as to those Claims is moot.

However, Claim 3 recited wherein the transgenic fish and the fish with different phenotype or pattern were of different family, genus or species. The requirement of different species has now been incorporated into Claim 1 following amendment as requested herein. Therefore, Applicants respectfully traverse this rejection with respect to new Claim 1.

# 4.2.1 No reasonable expectation of success

Applicants submit that there is at least no reasonable expectation of success. The Action has included Bartley to teach that "there are many different species of fish that can interbreed to form hybrid species and that hybrid species often can lead to more desirable traits including a variety of traits that make fish more profitable to raise...or that result in alterations in morphology." (present Action, page 8, lines 10-13). Although Bartley reports the possibility of inter-species mating, Bartley does not teach the success of inter-species mating of transgenic fish. When taking into account a transgenic manipulation, the result of mating is more unpredictable than that of two wild-type fishes, particularly since the present invention involves a fluorescent gene which is extrinsic to these fish and the introduction of the fluorescent gene is usually toxic to organisms. Moreover, Bartley recognizes the unpredictability of inter-species mating as stated above with respect to Claims 1, 2, 5-9 and 23.

Further, the present invention is the first suggestion of inter-species mating of transgenic fish carrying extrinsic and toxic fluorescent genes. Although Gong taught the use of transgenic fluorescent protein expressing fish as having ornamental value, the value of the present invention is actually beyond the scope of that of Gong's. The fish of the present invention is not merely a transgenic fish with fluorescence but a fresh water fish with characteristics that is comparable to a tropical fish popular in the aqua-market.

### 5. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that the present response is a full and complete response to the outstanding Action and that the application is in condition for allowance.

Serial No. 10/791,536 8964-000010/US Amendment E and Response to Office Action dated 11 January 2008

Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

John A. Castellano

Reg. No 35,094

P.O. Box 8910

Reston, VA/20195 (703)668-8000

JAC/MLC/LMR/pw